# FOOD SAFETY AND INSPECTION SERVICE
## PROGRAM FOR CERTIFYING NON-HORMONE TREATED BEEF TO THE EUROPEAN UNION
### Additional Program Requirements Outside the Scope of the Third Party Audited Process
### FSIS Inspector-in-Charge Responsibilities

**In order for the Food Safety and Inspection Service (FSIS) Inspector-in-Charge (IIC) to provide export certification for non-hormone treated beef and veal products destined to the European Union (EU), there must be assurances that effective controls in all phases of production comply with EU requirements. It is the responsibility of the IIC to ensure that the operations in the federally inspected, EU approved establishment comply with the requirements outlined in the most current EU Export Requirements and the Non-hormone Treated Cattle (NHTC) control programs are adhered to during EU production.**

## I. Operational Oversight

### *A.* Background material maintained by FSIS (Notebook: Non-Hormone Treated Cattle Program for Export to the European Union)

1. A current copy of the EU Export Requirements (located on HPDesk: OPENDESK/LIBRARY/EXPORT LIBRARY(31)/euroregs.txt)

2. A current list of EU Approved slaughter, cutting and storage establishments

3. A current list of Agricultural Marketing Service (AMS) approved producers and processors (The “Official Listing of Approved Non-Hormone Treated Cattle Producers and Processors” is available through the AMS web site or from the FSIS Technical Services Center, Import/Export/Program Analysis Staff, Omaha, NE)

4. Special letters/memorandums of instruction/Export Notices
    a. Related to reported violations in Europe (April – Nov 1999)

        (1) May 3, 1999 Memo (District Managers from Paul Thompson)

        (2) May 6, 1999 Memo (District Managers from Paul Thompson)

        (3) May 13, 1999 Memo (District Managers from Paul Thompson)

(4) June 14, 1999 Memo (District Managers from Paul Thompson)

(5) July 7, 1999 Memo (District Managers from Mark Manis)

(6) July 20, 1999 Memo (Export Notice 99-14)

(7) September 29, 1999 Memo (Export Notice 99-16)

(8) November 18, 1999 Memo (District Managers from Paul Thompson)

b. Instructions for the *"ADDITIONAL RESIDUE TESTING PROGRAM FOR FRESH MEAT EXPORTING TO THE EU- Directions for Sample Collection" (February 2001 or most current version)*

c. Any other correspondence related to the NHTC Program.

*5.* Copy of FSIS Guidelines to the Industry for Third Party Certification *(Program for Certifying Non-Hormone Treated Beef to the European Union (March 2000 or most current version))*

**B. Records and files maintained by FSIS IIC to assure identification, traceability and compliance with NHTC Program**

1. Background material in **"***Non-Hormone Treated Cattle Program for Export to the European Union***"** Notebook (listed above in section I.A.)

2. A copy of the establishment's written control program
   a. Each assigned IIC will sign and date the written program to verify knowledge of the program
   b. Subsequent changes will be signed and dated by IIC

3. A copy of AMS' "Official Listing of Approved Non-Hormone Treated Cattle Producers and Processors", reflecting the approval status of the producer of the cattle being presented for slaughter, as applicable.

4. Records of process controls
   a. Approved origin premises (farm/feedlot)

      (1) Must have an AMS assigned "NHTC approval number"

      (2) Reports of "internal audits" by establishment are on file with IIC.

b. Signed Affidavits

A signed affidavit must be available for every shipment of cattle to the slaughter establishment (producer affidavit) or every shipment of carcasses to the cutting establishment (transfer affidavit). A transfer affidavit is not required once the EU health mark is applied in a tamper evident fashion.

c. In-plant slaughter and processing records

(1) Written notification of EU mode of production from establishment management
(2) Daily record of EU production
Record on FSIS daily disposition records (FSIS form 6200-14) or any other comparable system for cross-referencing with other records (affidavits, ante-mortem cards and designated lot numbers.) If using FSIS form 6200-14, record this information on any open space on the front of the form or on the back (see enclosure 1.)
(3) Records of random verification activities, as needed (observations and subsequent action for non-compliance of EU requirements and controls)
(4) Copies of residue testing sample request forms submitted to the designated laboratories, along with reported results
(a) Additional Residue Testing Program, as assigned (FSIS form 10,210-3) (see instructions provided for “EU Notebook” under I.A.4.c.)
(b) Special NHTC Residue Testing Program, for every lot of NHTC produced (FSIS form 10,000-2) (see section II and enclosure 2.) NOTE: If the lot is sampled under the Additional Residue Testing Program, as assigned, then there is no need to duplicate the sampling under the Special NHTC Residue Testing Program.
(5) EU health mark storage and inventory control

### C. Additional Verification Activities

1. Verify EU cattle are segregated from any non-EU production and that unique animal identification controls are maintained.

2. Perform random verification activities throughout production to ensure compliance with control procedures.

   (a) Document observations, as needed.

   (b) Sign and date all establishment records that are reviewed during these random checks.

   (c) Oversight of establishment personnel's 100% palpation of the ears for implants through periodic verification during the production period.

3. Sample selection and collection for laboratory analyses, per instructions specific to the "Additional Residue Testing Program" and to the "Special NHTC Residue Testing Program".

4. Maintain complete control of samples until submitted to the designated laboratory for analyses.

5. On a periodic basis, review all plant management records from an entire lot for compliance with control procedures.

6. Non-compliance of EU requirements or controls
   (a) Notify establishment management
   (b) Request correction of deficiency
   (c) Withhold EU health mark label (or brand, if applicable) if non-compliance is not corrected

7. Issue export certification once assured that the production system is in compliance with the European Union requirements.

## II. Special NHTC Residue Testing Program

In April 1999, the European Union (EU) notified the Food Safety and Inspection Service (FSIS) that meat shipped to the EU labeled as "hormone-free" contained measurable levels of melengestrol acetate (MGA), zeranol or trenbolone. Each of these compounds is prohibited from use in beef intended for the EU. As a result of these concerns, FSIS initiated a special testing program to verify that each lot of cattle presented for slaughter was free of these compounds. This special monitoring program for 100% sampling of

the lots presented will continue on an interim basis, in addition to the "EU Additional Residue Testing Program" samples that are routinely requested.

NOTE: If a lot is sampled under the scheduled "Additional Residue Testing Program (using FSIS Form 10,210-3)" then no additional sample/testing is required for the "Special NHTC Residue Testing Program". All other lots presented for slaughter will be sampled following the instructions listed below.

**A. Sample Collection**

1. Observe animals ante-mortem, post-mortem, and during processing for any behavior and/or conformation related to the use of hormonal growth promotants (including injection or implant sites.) Target any animals for sample selection if any traits are observed, select samples and exclude from the program pending laboratory results.

2. Every lot of non-hormone treated beef or veal, as identified on the accompanying "producer affidavit" from an AMS approved NHTC producer must be sampled, unless the lot is sampled under the scheduled "Additional Residue Testing Program". (Note: Each lot of dairy or cull beef cows presented for slaughter intended for export to the EU must be sampled as well.)

   a. The FSIS Inspector-in-Charge (IIC) is responsible for selecting one animal from each lot to be sampled.
   b. The FSIS IIC is responsible for collecting the designated tissue sample.
      (1) MGA: 2 pound kidney fat—[to be sent to Maxxam Analytics, Inc., Canada (Maxxam) and the other half of the sample is to be held in frozen storage under FSIS control until negative results are received.]
      (2) Zeranol/Trenbolone: at least 120 ml urine (from the same animal, split into two samples)—[half of the sample is to be sent to Maxxam and the other half of the sample is to be held in frozen storage under FSIS control until negative results are received.]

3. Maintain all tissue samples under FSIS control until submitted to the designated laboratory.

**B. Completion of FSIS form 10,000-2 (Domestic Laboratory Report)**

1. Complete two FSIS form 10,000-2 in the normal manner, including the following entries:

   Block 10: Project Name: "EU Bovine Hormone Testing"

Block 15: Leave blank
Block 16: Name and address of producer on accompanying affidavit
Block 17: Bovine (beef or veal)

**For MGA:**
Block 19: Maxxam Analytics, Inc. (Canada)
Block 21: :Residue
Residue Class Code: 500
Specific Residue: Record this information in Block 24 if there is not enough space in Block 21: 504-MGA;
Block 22: :Fat

**For trenbolone/zeranol:**
Block 19: Maxxam Analytics, Inc. (Canada)
Block 21: :Residue
Residue Class Code: 500
Specific Residue: Record this information in Block 24 if there is not enough space in Block 21: 510-Zeranol; 515-Trenbolone
Block 22: :Other: urine

Block 23: Record any man-made identification device information, such as back tags, ear tags, tattoos, etc.
Block 24: Related information:
Record affidavit number (and date); number of animals in lot; sex of animals slaughtered; establishment slaughter lot number; slaughter date; and any other information pertinent to the identification of these animals. Record Specific Residue code in this section if there is not enough space in Block 21.
Block 25: Name of IIC

2. Copy distribution:

| | |
|---|---|
| Part 1,2 and 3: | Submit to the designated laboratory |
| Part 4: | Submit to the Technical Service Center, Residue Operations Staff, Suite 300, Landmark Center, 1299 Farnam Street, Omaha, NE 68102. Telephone: (800) 233-3935 Facsimile: (402) 221-7497. |
| Part 5: | Maintain in IIC file at establishment as a record of sample collection. Attach copy of producer affidavit and any other paperwork associated with the designated lot of EU cattle. |

## C. Submission of Samples

1. Freeze all specimens thoroughly prior to packing in containers provided by the establishment. [Note: do **NOT** use official FSIS shipping containers to ship these samples.]

2. Include the top three copies of FSIS form 10,000-2. For samples shipping to Canada: a copy of Canada's "Declaration of Importation" must be completed and attached to the outside of the shipping container. An example of this declaration and the instructions for completion is enclosed.

3. Cost of shipping is the responsibility of the establishment.

4. Submit samples for **MGA, trenbolone and zeranol** to:

   Maxxam Analytics Inc.
   c/o Tony Cheung
   5540 Macadam Road
   Mississauga, Ontario L4Z 1P1
   Canada
   Tel. (905) 890-2555

## D. Reporting Results

1. This program is designed as a monitoring program, so product is free to ship in advance of the results being reported.

2. The laboratory will provide a faxed copy of the report of the results to FSIS, International Policy Staff (IPS). IPS facsimile number is (202) 720-7990.

3. IPS will provide a copy of these results to FSIS, TSC, ROS, who will provide results to the IIC at the slaughter establishment. The IIC will file these results with the other documents related to the specific shipment.

4. If there are any detectable levels reported, IPS will provide detailed instructions on the action to be taken by the TSC and IIC at the establishment on a case-by-case basis.

Enclosures

References:

**FSIS Export Requirement Library**
http://www.fsis.usda.gov/ofo/export/explib.htm

**Agricultural Marketing Service/Livestock and Seed Program**
http://www.ams.usda.gov/lsg/mgc/nhtc.htm

**EU directives**

http://europa.eu.int/eur-lex/en/index.html